IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK® PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

DEFENDANTS' SUPPLEMENTAL EVIDENCE IN SUPPORT OF THEIR MOTION TO STRIKE PLAINTIFFS' EXHIBIT 620

I. INTRODUCTION

Defendants have filed a Motion to Strike Plaintiffs' Exhibit 620 – an affidavit executed by Dr. David Bliesner. (Doc. 579). Plaintiffs did not oppose the Motion to Strike; their response was due no later than September 26, 2011. Defendants, however, deposed Dr. Bliesner on September 19, 2011 in a Digitek® case pending in Oklahoma state court.[1] (*See* attached Ex. 4).[2] Defendants submit this supplemental evidence, learned during the recent deposition of Dr. Bliesner, in support of their Motion to Strike.

Dr. Bliesner's new testimony confirms his declaration is a "sham affidavit." Dr. Bliesner acknowledges that at least six of the departures from his Report that were made via testimony in his declaration are not correct, including critical, misleading references to out-of-specification Digitek® allegedly being released to market. Dr. Bliesner also undermines the reliability of the declaration himself and tries to distance himself from it. This Court should strike his declaration.

[1] *Sam Johnson, as Personal Representative of the Estate of Martha Bea Johnson, deceased v. Actavis Totowa LLC, et al.,* Dist. Ct. of Oklahoma Cty., Case No. CJ-2009-5292 ("*Johnson*"). The fact that Defendants were able to depose Dr. Bliesner in Johnson after the declaration was submitted to this Court does not alter the prejudice they suffered in this litigation. Defendants were not able to depose Dr. Bliesner regarding the declaration before they researched, drafted, and filed their various Motions and Replies, or before the Court's day-long hearing on these Motions in this litigation.

[2] To avoid filing any information which is even potentially confidential information of someone other than Actavis, Defendants have not filed the entire transcript of Dr. Bliesner's 9/19/11 deposition. Instead, Exhibit 4 to this Supplemental Evidence includes only the pages of the examination regarding Dr. Bliesner's MDL declaration.

II. ANALYSIS

A. Dr. Bliesner Did Not Draft His Declaration And Acknowledges It Contains Incorrect Testimony About Allegedly Defective Digitek®.

An email produced by Dr. Bliesner on September 19, 2011, which he received from Plaintiffs' counsel, indicates the declaration was drafted by Plaintiffs' attorneys:

> We were hit with 5 summary judgment motions and given very little time to oppose them. Bottom line, I think I will need a declaration from you setting forth some basic opinions about this case. We will prepare it and the facts will all come from your report and deposition transcript (which you will be able to verify)…

(Defs' Ex. 499 in *Johnson*, attached as Ex. 1).[3] Dr. Bliesner confirms he did not draft the declaration: "That document was -- with my input, a draft was created by either one of those two [Mr. Kilpatrick or Mr. Kerensky] to put it in proper legal format, because they realized that I didn't know anything about doing a motion." (Bliesner 9/19/11 Dep. at 186:13-20)

Dr. Bliesner made a few changes to the attorneys' draft – adding citations and inserting generic claims regarding a lack of Quality Assurance oversight. (*Compare* Pls' Ex. 620 with the original draft declaration attached to an email contained within Defs' Ex. 499 and revisions prepared by Dr. Bliesner in response to original draft, attached as Exs. 2, 3). Substantively, however, the document remained unchanged from the initial draft created by Plaintiffs' lawyers to the final version submitted as Plaintiffs' Exhibit 620. *Id.*

In ordinary circumstances, having counsel prepare a draft declaration and having the witness *actually* substantively review it before executing it might not be problematic, so long as it is really the testimony of the witness and is not impermissible lawyer briefing and arguing dressed up as affidavit testimony. Dr. Bliesner's testimony makes clear, however, that these are not ordinary circumstances. Much of the declaration testimony did not come "from [Dr.

[3] At his September 19, 2011 deposition, Dr. Bliesner produced a portable hard-drive containing various documents. The hard drive and all of its contents – including this email and an email Dr. Bliesner sent to Plaintiffs' counsel with some revisions to the draft declaration – was marked as Defendants' Exhibit 499.

Bliesner's] report and deposition transcript" and Dr. Bliesner plainly did not "verify" the testimony before he executed the affidavit. Rather, Dr. Bliesner's declaration contains repeated references to *defective* Digitek® which were prepared by Plaintiffs' lawyers, were not in Dr. Bliesner's Report, and which Dr. Bliesner now acknowledges are inaccurate.

In particular, Dr. Bliesner confirms that the testimony in his declaration bullet point #12, which reports that Mylan had two batches of Digitek® – in the market – "with out-of-specification assays (too low)," was incorrect and is "an error." (Bliesner 9/19/11 Dep. at 195:18-25; *see* Pls' Ex. 620 at 4). He did not refer to these two batches as out-of-specification in his Report because the two batches were *within* specification. (Bliesner 9/19/11 Dep. at 194:7-195:14). Dr. Bliesner also confirms that the testimony in his declaration bullet point #8 that there were "blend uniformity defects" in batch 60319 is another "error." (Bliesner 9/19/11 Dep. at 203:17:-204:1; *see* Pls' Ex. 620 at 4). His Report did not describe batch 60319 as having a blend uniformity defect because the relevant Actavis document made clear it was not defective. (Bliesner 9/19/11 Dep. at 202:7:-203:1). Indeed, prior to recanting his testimony, this declaration marked the first time in Dr. Bliesner's 19 year career in the industry that he had used the term "defect" to describe something that was not out-of-specification. (*Id.* at 199:10-13).

Declaration bullet point #17 indicates the 2008 Digitek® recall occurred "*due* to double thickness tablets, overweight tablets, *and/or blending defects*." (*See* Pls' Ex. 620 at 5) (emphasis added). Dr. Bliesner concedes that neither the recall notice nor his Report say anything about "blending defects" as a basis for the recall and that the "blending defects" testimony in his declaration is more inaccurate testimony "prepared" by Plaintiffs' counsel. (Bliesner 9/19/11 Dep. at 223:5:-225:15). Likewise, in declaration bullet point #16, Dr. Bliesner testifies that the 2008 FDA inspection of Actavis was "*due to* 'significant cGMP deficiencies' relating to the

prevention and remediation of double-thick tablets and blending failures." (*See* Pls' Ex. 620 at 4) (emphasis added). Dr. Bliesner, however, had not previously attributed the inspection to these issues. (Bliesner 9/19/11 Dep. at 225:16:-226:22). In fact, he now concedes that the reason the FDA inspected Actavis in 2008 was "clearly not" for the reasons set forth in his declaration and that this testimony was "an incorrect statement." (Bliesner 9/19/11 Dep. at 227:21-228:4).

With respect to batch 70924 (the batch which contained the double-thick tablets that were noticed during production and removed prior to release to market), declaration bullet point #10 indicates the batch was released to market on December 5, 2007, "[f]ollowing a rapidly conducted visual inspection[.]" (*See* Pls' Ex. 620 at 4). The visual inspection was conducted over a 4 day period in January, 2008. Dr. Bliesner now concedes the batch was released no earlier than late January, 2008. (Bliesner 9/19/11 Dep. at 219:11-24). This was not a casual mistake. In his Report, Dr. Bliesner still gets the date wrong but says, merely, "product was released to market on 5 December 2007." (Bliesner 9/19/11 Dep. at 220:7-11). When Plaintiffs' counsel prepared the declaration, they added "following a rapidly conducted visual inspection[.]" Dr. Bliesner signed this modified description, incorrect release date and all. (Bliesner 9/19/11 Dep. at 220:21-221:1; Pls' Ex. 620 at 4).

This incorrect testimony is particularly troubling. Dr. Bliesner describes double-thick tablets as "the crux" of this litigation, and the document at issue is the complete report of the internal manufacturing investigation by Actavis into the double-thick tablet situation. (Bliesner 9/19/11 Dep. at 217:5-6; *see* Pls' Ex. 16). This document is among the most significant documents in this litigation and is crucial to any analysis of whether there are defective tablets in the market. Nevertheless, Dr. Bliesner read this critical document incorrectly and is willing to give inaccurate testimony prepared by Plaintiffs' counsel which he easily could have verified.

Dr. Bliesner also testifies that, after the recall, "Actavis did not test, examine or do anything to determine the magnitude of their manufacturing problem of out of specification Digitek tablets. They simply stored the recalled product in a warehouse and kept on producing Digitek." (Pls' Ex. 620 at 9). This is another "error" – Actavis never produced Digitek® after the recall. (Bliesner 9/19/11 Dep. at 280:9:-281:3).

Dr. Bliesner's declaration contains significant testimony that mis-characterizes certain Digitek® as defective and that also mis-characterizes the nature of the 2008 FDA inspection and the Digitek® recall. None of this testimony was in Dr. Bliesner's Report; it was all drafted by Plaintiffs' counsel and, unfortunately, validated by Dr. Bliesner in his lawyer-prepared declaration. Dr. Bliesner now confirms it is all incorrect.

B. Dr. Bliesner Discredits His Own Affidavit.

Confronted with these many errors, Dr. Bliesner tries to excuse the errors and distance himself and his Report from the declaration. His primary justification is that he had a large volume of documents to review which were not organized or necessarily related to each other.

> How do you make a mistake like that? When you're reviewing thousands and thousands and thousands of documents that have -- pages of documents that have no lineage or connection to it, it's very easy to get a date messed up. That's how you mess it up. And then the basis for the report, errors are propagated and goes into a summary like this [declaration]. That's how it happens.

(Bliesner 9/19/11 Dep. at 221:5-13). Likewise, Dr. Bliesner conducted "a review of various other documents that are all thrown together and handed out in piecemeal fashion..."[4] (Bliesner 9/19/11 Dep. at 229:7-11). He also says the declaration was prepared without someone else performing a quality check: "In an analytical chemistry environment and in the pharmaceutical

[4] Dr. Bliesner's comments also speak directly to the reliability of his overall methodology and conclusions – Dr. Bliesner would never conduct an evaluation of whether a product was defective in his private consulting practice by reviewing thousands of pages of documents that "have no lineage or connection to [the issue]" and were "thrown together and handed out in piecemeal fashion."

industry in general, a document like this would have a second-and a third-party review for content." (Bliesner 9/19/11 Dep. at 228:24-229:2).

Dr. Bliesner makes clear he has known there were errors – which he has not corrected with the Court – since he signed the declaration:

> As we talked about very early on in the deposition, I pointed out that I knew that there were errors in this report after I -- the declaration, after I signed it.
> ...
> There are. There are. I wouldn't classify it as quite a few, considering the volume of documents that built up the original report to go into this [declaration] as a summary. There are errors. I, I'm not going to say that there aren't.

(Bliesner 9/19/11 Dep. at 228:9-19).

To underscore his own lack of reliance on the declaration, Dr. Bliesner twice deliberately characterizes his declaration as a "summary." (*Id.* at 221:12, 228:18). Finally, asked directly whether he validates the declaration, Dr. Bliesner says "No." (*Id.* at 224:16).

III. CONCLUSION

Dr. Bliesner's casual assertion that the many instances of incorrect sworn testimony in his declaration are nothing more than "errors" that should be expected in such a complex review raises more questions than it answers. Understandably, Dr. Bliesner now wants to put some distance between himself and the declaration. This Court should do the same. This is precisely the kind of late filed effort to change prior testimony and prop up a case the "sham affidavit" cases frown upon.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2011, a copy of the foregoing **DEFENDANTS' SUPPLEMENTAL EVIDENCE IN SUPPORT OF THEIR MOTION TO STRIKE PLAINTIFFS' EXHIBIT 620** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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